UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,937	10/07/2003	Thomas B. Stanford JR.	B-4588NP 620930-1	6021

7590 03/25/2008

Richard P. Berg, Esq.
c/o LADAS & PARRY
Suite 2100
5670 Wilshire Boulevard
Los Angeles, CA 90036-5679

EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/680,937	STANFORD ET AL.	
	Examiner	Art Unit	
	PAUL C. MARTIN	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16,17,19-27 and 29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16,17,19-27 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 14, 16, 17, 19-27 and 29-32 are pending in this application and were examined on their merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/14/08 has been entered.

The rejection of Pending claims 14, 16, 17, 19-27 and 29-32 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn due to the Applicant's amendments to the Claims filed 01/14/08.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14, 16, 17, 19-27 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keyes (US 4,169,765) in view of Yamagishi *et al.* (US 6,730,212 B1).

Keyes teaches method for the detection of α-amylase produced by an organism (for example, in blood serum) using a sensor comprising a substrate-surface immobilized amylose starch reagent is contacted with a sample containing α-amylase expressed by an organism, the α-amylase catalyzes the reaction of starch to form oligosaccharides which react with immobilized glucoamylase to form glucose, glucose oxidation is catalyzed by immobilized glucose oxidase to form gluconic acid and H_20_2, wherein the amount glucose is measured by detecting the amount of current generated by the H_20_2 with an electrode (Column 4, Lines 1-20 and Column 30, Claims 1-3).

Keyes does not teach a method wherein a sol gel matrix covers a glass substrate and the electrodes, wherein the electrodes are interdigitated and comprise gold, and the sol-gel comprises tetramethoxy orthosilicate and encapsulates the glucose oxidase, reactant and transducer material, wherein the generated H_20_2 modulates the electrical resistance of an inherently conductive, water-soluble polyaniline polymer transducer.

Yamagishi *et al.* teaches a sensor comprising a glass substrate on which multiple pairs of interdigitated, gold comprising electrodes are deposited, covered by a sol-gel matrix containing the inherently conductive, water-soluble polyaniline polymer tetramethoxy orthosilicate (TMOS) and encapsulating multiple enzymes (glucose oxidase), wherein glucose oxidation is catalyzed by the glucose oxidase to form gluconic acid and H_20_2 modulating the electrical resistance of the conductive polymer detected by applying voltage and registering the change in current with an amperometer (Column 3,Lines 30-61 and Column 5, Lines 45-50 and Columns 15 and 16, Claims 1-3 and Column 17, Claims 9-12 and 14).

Yamagishi *et al.* teaches that prior sensor methods including surface acoustic wave, mass spectroscopy, infrared spectroscopy and gas chromatography are directed toward laboratory analysis rather than field application and have the disadvantages of having large size, long analysis times, complicated electronics support, lack of specificity and high cost (Column 2, Lines 57-67) while the enzyme-encapsulated, conductive polymer sol-gel biosensor has the advantages of being simple, inexpensive, accurate and adaptable to field detection of biological pathogens or chemical agents without the need for "wet" chemistry (Column 3, Lines 1-13).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the enzyme immobilized sensor method for the detection of α-amylase produced by an organism as taught by Keyes above with the enzyme-encapsulated, conductive polymer sol-gel biosensor as taught by Yamagishi *et al.* above because both methods are drawn to the use of immobilized enzymatic biosensors in the detection and measurement of an environmental enzyme of interest. One of ordinary skill in the art would have been motivated to make this combination because of the advantages described by Yamagishi *et al.* above, such as being simple, inexpensive, accurate and adaptable to field detection of biological pathogens or chemical agents without the need for "wet" chemistry.

One of skill in the art would have recognized that the use of an ohmmeter to measure the electrical resistance instead of the ammeter used to measure current as taught by Yamagishi *et al.* would have been a matter of preference as both methods are used to determine electrical current. In particular, the method of Yamagishi *et al.* is advantageous over the solitary method of Keyes, which relies on laboratory specific analytical techniques such as polarography, mass spectroscopy and "wet" chemistry. There would have been a reasonable expectation of success in making this combination because both methods rely upon substrate immobilized enzyme technology, particularly the use of glucose oxidase in the oxidation of glucose to form gluconic acid and hydrogen peroxide and the measurement of the electrical current derived from this reaction.

One of ordinary skill in the art would have recognized that giving the claims their broadest, reasonable interpretation the method of the combined teachings of Keyes and Yamagishi *et al.* would meet all of the claimed limitations of the instant invention. The language relating to the "...the method comprising assaying a plurality of enzymes with a sensor to determine a suite of enzymes expressed by an organism..." amount to a statement of intended use that does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Further, one of ordinary skill in the art at the time of the instant invention would have recognized that the new limitations added to claim 14 that require the sensor to comprise more than one pair of electrodes, a sol-gel matrix comprising more than one sol-gel enzyme and associated with at least one of the more than one pair of electrodes, would have been obvious. As the combination of Keyes *et al.* and Yamagishi *et al.* teach an enzyme sol-gel immobilized sensor method for the detection of α-amylase produced by an organism using a single electrode, it would have been obvious to combine an array of multiple enzymes and associated electrodes as a means of screening for multiple organism enzymes in one assay and thereby advantageously increasing the cost and time efficiency of the multi-enzyme screening assay.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

03/06/08

/Jon P Weber/

Supervisory Patent Examiner, Art Unit 1657